

SEP 25 2000

Attachment 1

510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K001958

1. Submitter's Identification:

Len Manicini, President
Keystone Medical
1338 Michael Way
Lansdale, PA. 19446

Date Summary Prepared: June 15, 2000

2. Name of the Device:

Keystone Medical Schon XL Soft-Line double lumen catheter
Keystone Medical 12 F Duo-Flow and 14F Duo-Flow 400 XL catheter

3. Predicate Device Information:

These devices are substantially equivalent to devices currently marketed by Medical Components, Inc, Lansdale, PA under K974236. Medical Components will continue to manufacture these devices.

4. Device Description:

Catheters used to remove and return blood through two-segregated lumen passages. Each lumen is connected to an extension line with color-coded female luer connections. The transition between lumen and extension is housed within an over molded soft hub. Catheter tip is formed from soft polyurethane. The lumens are manufactured so as the venous lumen runs coaxial within the arterial lumen. The venous lumen communicates with the blood stream through the distal tip hole, and a series of 4 side holes. The arterial lumen communicates with the blood stream via 4 side holes

5. Intended Use:

The Keystone Medical catheters are designed for acute hemodialysis and apheresis. They may be inserted percutaneously and are ideally placed in the internal jugular vein. Although these catheters may be inserted into the subclavian or femoral vein, the internal jugular is the preferred site.

6. **Comparison to Predicate Devices:**

The Keystone Medical Lumen catheter is identical to the predicate.

The Keystone device will differ only in that the Keystone Medical name and logo will appear on the unit labels, box labels, and instructions for use. Keystone will also develop it's own sell sheets for these devices in the future.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non clinical testing was completed to support K974236, and was included with this 510(k) submission

8. **Discussion of Clinical Tests Performed:**

Clinical testing was not completed

9. **Conclusion**

The Keystone Medical Schon XL Soft-Line double lumen catheter and Keystone Medical 12 F Duo-Flow and 14F Duo-Flow 400 XL catheters are safe and effective for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2000

Keystone Medical
c/o Mr. Alan P. Schwartz
Official Correspondent for Keystone Medical
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K001958
Keystone Medical 12F Duo-Flow and 14F Duo-Flow
400 XL Catheters, 12cm, 15cm, 20cm and 24cm
Regulatory Class: II
21 CFR §876.5540/Procode 78 MPB
Dated: June 26, 2000
Received: June 27, 2000

Dear Mr. Schwartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

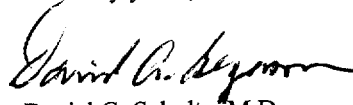
FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used in the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

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1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for 

Daniel G. Schultz, M.D.
Captain, USPHS

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K001958

Exhibit B

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510(k) Number (if known): K001958

Device Name: Keystone Medical 12 Duo-Flow and 14 F Duo-Flow 400XL Catheter

Indications For Use:

The Keystone Medical 12 Duo-Flow and 14 F Duo-Flow 400XL Catheter are designed for acute hemodialysis and apheresis. They may be inserted percutaneously and are ideally placed in the internal jugular vein. Although these catheters may be inserted into the subclavian or femoral vein, the internal jugular is the preferred site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Sygorn
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K001958